

III. REMARKS

The amendments submitted herein should be understood to be made as a practicality only, and should not to be construed as creating any situation of file wrapper estoppel or the like as all rights are expressly reserved and may be pursued in this or other applications, such as divisionals, continuations, or continuations-in-part if desired. Relatedly, it should be understood that the amendments made herein are made for tangential issues of clarity and as a matter of the Office's convenience or expedience only. The amendments should not be interpreted as an action that in any way surrenders a particular equivalency, surrenders any right to patent coverage, or otherwise limits any rights which the Assignee may now or hereafter assert. It should be understood that, unless and to the extent deemed broadened by this amendment, and even as amended, the Assignee expressly reserves all rights, including but not limited to: all rights to maintain the scope of literal coverage with respect to any element as may have existed under the language previously presented, all rights to maintain the scope of equivalency coverage as may have existed under the language previously presented, and all rights to re-present the prior language at any time in this or any subsequent application. To the extent currently foreseeable, no change or reduction in direct or equivalency coverage is believed to exist, and no change or reduction in direct or equivalency coverage is intended through the presentation of this amendment.

The Assignee amends the claims to convey that that the sperm cells are from a species of a non-human male mammal.

35 U.S.C. § 112 Concerns

The action expressed concerns to the claims under 35 U.S.C. § 112 First and Second Paragraphs. Claim 38 and newly added claims 68 and 69 reference the aspect of sperm cells in an extender suspended to at least about 5 million per milliliter of extender to at least about 10 million per milliliter of extender, about 5 million per milliliter of extender to about 10 million per milliliter of extender, or about 5 million per milliliter of extender to about 20 million per milliliter of extender. The values and results shown in Table 1 on page 21 and to some degree in

Table 2 on page 19 highlight how the claimed ranges show significance in the data. Referencing Table 1, it can be seen how the results increase to a more consistent value when the dilution is established at values of at least about 5 million per milliliter of extender to at least about 10 million per milliliter of extender or higher. Thus, the Table 1 values support the claimed ranges as one skilled in the art can appreciate. Supplemental data will be provided to further support this.

In addition, to clarify the examiner's concerns regarding the reference to 5 million per milliliter and 10 million per milliliter of extender, Assignee specifies that these numbers relate to the concentration of sperm in an extender as discussed in the specification.

Claim 38 also references the aspect of cooling sex-selected sperm cells. As previously stated and to clarify the examiner's concerns regarding cooling, sperm cells can be cooled under suitable conditions within the level of skill in the art. As a non-limiting example, sperm can be cooled to 5 degrees Celsius. Of course, other temperatures may be used as one skilled in the art can appreciate.

Claim 43 references the aspect of utilizing between about 1,000,000 and about 25,000,000 equine sperm. As previously stated, various dosages and amounts are discussed in the specification. The volume of the straws used for insemination is also mentioned as both 0.25 ml and 0.50 ml at page 17 beginning on line 30 among other locations. Applying the extension mentioned in the specification at page 11 beginning at line 26 and at page 22 beginning at line 8 with these volumes of straws, it can be understood that sperm dosages of 1,250,000 (2.5×10^6 /ml in a 0.50 ml straw) and 25,000,000 (50×10^6 /ml in a 0.50 ml straw) were used. Further, at page 47 beginning at line 17, at page 48 beginning at line 5, at page 51 beginning at line 17, at page 52 beginning at line 25, and also at page 53 beginning at line 4, the use of 1,000,000 (1×10^6) sperm is explicitly mentioned. Assignee also notes that in the affidavit by John L. Schenk filed January 20, 2006, he stated that, "since the Original Application mentions concentrations of sperm of 1,000,000 and 25,000,000 (50×10^6 /ml in a 0.50 ml straw), the Original Application supports the claimed range of the concentrations of between about 1,000,000 to about 25,000,000 based on the substantial variation of doses that may be required." Accordingly,

support for the claimed ranges is found in the specification as one skilled in the art can appreciate.

Claim 64 mentions the aspect of equilibrating for a period of not greater than 6 hours. This aspect is found in the specification on page 17 lines 7-8. Assignee also notes that in the affidavit by John L. Schenk filed January 20, 2006, he stated that, “with respect to claim 64, I understand the text of the Original Application when it states, “to about 6 hours” to describe equilibrating for a period of not greater than 6 hours.” Accordingly, these claimed time limits are supported by the specification as one skilled in the art can appreciate. Further, the action expresses concerns to claims 63 and 64. Assignee believes that these concerns are clarified since both claims 63 and 64 now include, *inter alia*, “equilibrating … *prior to said freezing step (e)* …” (emphasis added).

In addition, claims 63 and 64 mention equilibrating sex-selected sperm cells to a cooler, non-freezing temperature. As previously stated and to clarify the examiner’s concerns regarding cooling, it may be desirable to cool the temperature of the sperm cells suspended in an extender to any temperature above freezing. As a non-limiting example, sperm can be cooled to 5 degrees Celsius. Of course, other temperatures may be used as one skilled in the art can appreciate.

35 U.S.C. § 103 Concerns

The action expressed concerns to the claims under 35 U.S.C. § 103. A *prima facie* case of obviousness requires that the combination of references disclose all of the limitations of the claimed invention. As the claims are currently stated, the prior art does not include all of the elements nor limitations of each of the independent claims 38, 68, or 69.

To respond to the action’s questions, Table 1 of the specification shows the sperm motility relationships for incubation times of 24 hours and 48 hours at different dilutions. Of course, sperm motility can decrease at 48 hours as compared to 24 hours, as one skilled in the art would appreciate. As previously stated, percentages of sperm motility increased as the sperm

concentration increased to 10×10^6 / ml (e.g. 61% at 24 hours), (more consistently between 5×10^6 / ml and 10×10^6 / ml) but there was little difference thereafter as seen in Table 1.

As previously noted, the claims are at this stage are distinguished from the references through their inclusion of the element of sorting the sperm cells without the presence of protective compounds in seminal plasma and suspending at dilutions of about 5 million per milliliter of extender to about 10 million per milliliter of extender, at least about 5 million per milliliter of extender to at least about 10 million per milliliter of extender, or about 5 million per milliliter of extender to 20 million per milliliter of extender. These techniques are not mentioned in the references at the dilutions as set forth. Assignee refers to the discussion above relating to the concentrations of sperm in the extender. Assignee also notes that in the affidavit by John L. Schenk filed January 20, 2006, it is noted the he "believe[s] that the techniques taught in the Spaulding and Shrimpton references are not capable of being successfully reproduced." Accordingly, the references do not address the aspects claimed and the section 103 concerns are not believed appropriate.

The Assignee believes all concerns raised in the February 9, 2006 office action have been addressed as best understood. Reconsideration and allowance of these remaining claims is respectfully requested at the Examiner's earliest convenience. Finally, should the Examiner have any remaining questions or disagree with any of Assignee's explanations, it is requested that the Examiner contact the undersigned by telephone in order to expedite the processing of this application.

Dated this 9 day of August, 2006.

Respectfully submitted,
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IN THE UNITED STATES PATENT AND
TRADEMARK OFFICE

Application Number: 09/478,299
Applicants: John L. Schenk
Filed: January 5, 2000
Title: Method of Cryopreserving Selected Sperm Cells
Group Art Unit: 1654
Examiner: M. Meller
Assignee: XY, Inc.
Attorney Docket: 22091-701
Customer No.: 33549

CERTIFICATE OF EXPRESS MAILING

I, Cheryl A. Swanson, hereby certify to the truth of the following items:

1. I am an employee of Santangelo Law Offices, P.C., 125 South Howes, Third Floor, Fort Collins, Colorado 80521.

2. I have this day deposited the attached Request for Continued Examination under 37 C.F.R. § 1.114 with the United States Postal Service as Express Mail, postage prepaid, for mailing to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated this 9 day of August, 2006.

Cheryl A. Swanson
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